

accordance with the invention, a medical balloon may be disposed between the inflatable members of any of the inventive devices disclosed herein and the medical balloon at least partially inflated. The inflatable members are then inflated so that the balloon contacting portions deform portions of the medical balloon inward. The medical balloon is at least partially deflated and desirably, completely deflated with the inwardly deformed portions of the medical balloon forming a plurality of balloon folds. Finally, the inflatable members are removed from about the medical balloon.

[0017] In another embodiment of the inventive method, a catheter comprising a medical balloon is provided and a plurality of inflatable members are disposed about the medical balloon. Each inflatable member has a balloon contacting portion. The balloon is at least partially inflated by supplying an inflation fluid thereto and the inflatable members are at least partially inflated so that the balloon contacting portions contact the medical balloon and apply an inward force to the medical balloon. At least some of the inflation fluid may be removed from the medical balloon and the inflatable members may be removed from about the medical balloon. Desirably, the inflatable members are configured to apply a radially inward force to the medical balloon when they are inflated. More desirably, the inflatable members are symmetrically disposed about the medical balloon and upon inflation apply a sufficient radially inward force to the medical balloon to form a plurality of indentations in the medical balloon. The medical balloon upon removal of the inflation fluid therefrom has a plurality of folds.

[0018] In yet another embodiment of the inventive method, a catheter comprising a medical balloon may be provided. An inflatable member with a plurality of balloon contacting portions is disposed about the medical balloon. The inflatable member is at least partially inflated so that the balloon contacting portions of the inflatable member contact the medical balloon and apply an inward force to the medical balloon. The medical balloon may be at least partially deflated and desirably completely deflated and the medical balloon removed from between the balloon contacting portions.

[0019] In accordance with the inventive methods, the inward force may be applied to the balloon in a variety of ways. For example, the inward force may be applied progressively along the length of the balloon. This may be accomplished by providing inflatable members which have inflation lumens which open into the inflatable members at a first end of the device and a balloon which has an inflation lumen which opens into the

balloon at the second end of the device, opposite the first end of the device.

[0020] Further in accordance with the inventive methods, the inflatable members may be inflated simultaneously or in a predetermined sequence. As an example of the latter, where the plurality of inflatable members includes a first inflatable member located at a first end of the balloon, a second inflatable member located at the middle of the balloon and a third inflatable member located at a third end of the balloon, the second inflatable member may be inflated prior to the first and third inflatable members to configure the middle of the balloon prior to configuring the ends of the balloon. As another example of the latter, the inflatable member may be inflated prior to the second inflatable member which may be inflated prior to the third inflatable member to progressively configure the balloon from one end to the other end.

[0021] The invention is also directed to a method of configuring at least a portion of a medical balloon comprising the steps of providing a catheter comprising a medical balloon, at least partially inflating the medical balloon, applying a plurality of discrete axially spaced inward forces to the medical balloon and deflating the medical balloon. Suitably, the plurality of discrete forces are applied by a plurality of inflatable members axially spaced along the balloon. The plurality of discrete forces may be applied simultaneously with one another or in a predetermined sequence.

[0022] The inventive methods may be used to provide folds along the entire length of the balloon or along a portion of the length of the balloon. The inventive methods may be used to provide folds with complex shapes such as spirals as well as other complex shapes.

[0023] The invention is also directed to a medical balloon comprising a pleat, at least a portion of which extends in a direction which is non-parallel to the longitudinal axis of the balloon. Desirably, the pleat has a first end and a second end, the first end circumferentially and longitudinally displaced from the second end of the pleat. In one embodiment, the pleat spirals at least partially about a longitudinal axis of the balloon. The balloon may optionally comprise a plurality of pleats each of which has a first end and a second end which is circumferentially and longitudinally displaced from the first end. The pleats may be longitudinally discontinuous or continuous.

[0024] The invention is also directed to a medical balloon having a body portion with a first

region with pleating and a second region with pleating where the second region is axially displaced from the first region and the pleating in the second region differs in appearance from the pleating in the first region. The pleating in the second region may differ in appearance from that of the first region as a result of discontinuities between the pleating in the first and second regions. The appearance of the pleating in the first and second regions may also differ in that the number of pleats in the first region differs from the number of pleats in the second region. It is also within the scope of the invention for the shape of the pleating in the different regions to differ. The medical balloon may optionally comprise additional pleated regions where the appearance of the pleating differs from the appearance of the pleating in other regions.

[0025] The invention is further directed to medical balloons manufactured using any of the inventive techniques disclosed herein.

[0026] Additional details and/or embodiments of the invention are discussed below.

Brief Description of Drawings

[0027] Fig. 1 is an exploded view of an inventive device for configuring an inflatable balloon in accordance with an embodiment of the invention.

[0028] Fig. 2 shows a plurality of inflatable members for use in the inventive device of Fig. 1.

[0029] Fig. 3 shows a cross-sectional view of the inventive device of Fig. 1 taken along line 3-3.

[0030] Fig. 4 shows a cross-sectional view similar to that of Fig. 3 of an inventive device having pie-shaped inflatable members.

[0031] Fig. 5 shows a cross-sectional view similar to that of Fig. 3 of an inventive device having circular inflatable members.

[0032] Fig. 6 shows a first end view of the inventive device of Fig. 1.

[0033] Fig. 7 shows a second end view of the inventive device of Fig. 1.

[0034] Fig. 8 shows a cross-sectional view of a balloon and an inflatable member.

[0035] Fig. 9 shows an inventive device with inflatable members disposed at an angle relative to the balloon.